K020607

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BIOMEC

A BIOMEDICAL PRODUCT DEVELOPMENT AND COMMERCIALIZATION COMPANY

510(K) Summary
Safety and Effectiveness Data Summary

Prepared By:	BIOMEC Inc. 1771 E. 30th Street Cleveland, OH 44114 USA
Telephone Number: **Fax Number:**	216.937.2800 216.937.2812
Contact Person:	Tracey H. Wielinski, RAC
Proprietary Name: **Classification Name:** **Common Name:**	SleepFLO Ventilatory Effort Recorder Airflow Sensor
Classification: **Regulation Number:** **Product Code:**	Class II 868.2375 MNR, BZQ
Performance Standards:	EN 60601-1 Medical Electrical Equipment- Part 1: General Requirements for Safety EN 60601-1-2 Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic compatibility - Requirements and tests
Substantial Equivalence:	Pro-Tech Pressure Transducer Airflow Sensor 510(k) Number: K982293 Pro-Tech SPI Sensor 510(k) Number: K940013 Pro-Tech Crystal Trace® Piezo Respiratory Effort Sensor 510(k) Number: K923402

Description of the Device:

The SleepFLO device is a compact breathing sensor used during sleep disorder diagnosis procedures. The device senses airflow, snore (derived from the airflow), body position, thoracic effort, and abdominal effort. The device consists of two enclosures - a sensor unit and a battery unit, and two respiratory effort belts. A 7-foot, eight-conductor cable connects the sensor unit and the battery unit; a 1-foot two-conductor cable connects each of the respiratory sensor belts to the sensor unit.

The sensor unit houses the airflow pressure sensor, the body position sensors, and the connectors for both effort belts (abdominal and thoracic). Airflow is measured using a pressure-based technique. Patients wear a nasal cannula that carries breathing air fluctuations to a pressure sensor inside the sensor unit. The cannula attaches to the sensor unit via a luer lock. The pressure measurements are used to indicate airflow and to derive the snore output. The cannula is a one-time use device and contains a 0.2-micron filter. The position sensors utilize miniaturized ball switches that detect five body positions: upright, supine, prone, left, and right. The effort belt connectors (thoracic and abdominal) are used to pass the signal of the effort belts to the polysomnograph system (PSG) device.

The two respiratory effort belts use a piezoelectric sensor attached to an elastic belt. The elastic sensor belt is held in place with a Velcro® strap about the thorax and abdomen.

The battery unit houses the snore detection circuitry, the connectors to the PSG, and the batteries that power the device (both the sensor unit and the battery unit). The sensor unit signals (airflow, thoracic effort, abdominal effort, and body position) are passed to the battery unit via the interconnecting eight-conductor cable. The battery unit receives these signals and delivers them to the appropriate output cables, which are connected to the PSG. In the case of the snore, the airflow signal is band pass filtered to generate a snore signal, which is then passed to the PSG via the snore output cable.

The connections to the PSG junction box are accomplished via five (5) pairs of cables. All five-cable pairs are terminated with standard PSG plugs (1.5 mm recessed). The battery compartment can be attached to the junction box with Velcro®.

Intend d Use:

SleepFLO is intended for use during sleep disorder studies to detect up to five breathing signals: airflow, body position, thoracic effort, abdominal effort and snore.

Patient Population:

SleepFLO can be used to monitor the respiration for patients who are candidates for Sleep Diagnostic evaluation. SleepFLO is indicated for use in patients two (2) years and older. The device is not indicated for use in infant or pediatric patients less than two (2) years of age. SleepFLO is not for use by pediatrics and infants below two years of age for SIDS monitoring.

Safety and Effectiveness:

The maximum voltage inside the SleepFLO is 3-volts DC. This is because the device uses two (2) AA batteries in series. There are no direct electrical connections to the patient since the airflow pressure input uses a cannula made from non-conducting plastic, the respiratory sensor belts use an insulated piezoelectric device surrounded by cloth material for comfort, and the body position sensors are housed inside a non-conducting plastic enclosure. The maximum output voltage for all five (5) signals is 1-volt. Due to these low voltages and the insulation material, there is no danger to the patient or provider of serious injury due to electrical shock.

The cannula is a single use only device with a 0.2-micron hydrophobic filter permanently attached. Due to the single use only cannula and integral filter, there is no danger to the patient of serious illness due to cross contamination.

The SleepFLO device was used in place of the predicate devices in laboratory and clinical testing. These tests showed that the electrical output signals from the SleepFLO device provided equivalent informational content as the electrical output signals from the predicate devices. The testing compared respiratory airflow and effort along with body position and snore.

Summary of Technological Characteristics:
The following comparison is provided as a summary of the technological characteristics relative to the predicate devices. This is to demonstrate that

the BIOMEC SleepFLO has no significant differences from the predicate devices that would adversely affect product safety and effectiveness.

Comparison Parameter	**BIOMEC SleepFLO**	**Pro-Tech PTAFlite**	**Pro-Tech SPI Sensor**	**Pro-Tech Crystal Trace Piezo Respiratory Effort Sensor**
Intended Use	Intended for use during sleep disorder studies to detect up to five breathing signals: airflow, snore, thoracic effort, abdominal effort, and body position for recording onto a physiological recorder.	Intended for use during sleep disorder studies to detect respiratory airflow and snoring via nasal pressure changes for recording onto a physiological recorder.	Intended for use in sleep disorder testing to detect positions of sleep and to provide an output voltage for recording onto a compatible computerized polygraph.	Intended for use during sleep disorder studies to detect respiratory effort for recording onto a physiological recorder.
Population	2 yrs and older	2 yrs and older	2 yrs and older	2 yrs and older
Number of Channels	4 inputs (air pressure, abdominal effort, thoracic effort, and body position)	1 input (air pressure)	1 input (body position)	2 Inputs (abdominal and thoracic effort)
	5 outputs (airflow, snore, abdominal effort, thoracic effort, and body position)	2 outputs (airflow & snore)	1 output (body position)	2 outputs (abdominal and thoracic effort)
Method of Connection to Patient	Plastic tubing and cannula set for airflow and snore.	Plastic tubing and cannula set for airflow and snore.		
	Elastic cloth material for effort belts (2).			Elastic cloth material for effort belts (2).

Comparison Parameter	BIOMEC SleepFLO	Pro-Tech PTAFlite	Pro-Tech SPI Sensor	Pro-Tech Crystal Trace Piezo Respiratory Effort Sensor
	Body position sensors enclosed in plastic case, which attaches to respiratory effort belt.		A padded sensor pillow, which mounts to most respiratory effort belts.	
Safety Characteristics	Connects to physiological recorder.	Connects to physiological recorder	Connects to physiological recorder.	Connects to physiological recorder
	Uses plastic tubing to insure patient isolation.	Uses plastic tubing to ensure patient isolation		
	Uses a 0.2-micron hydrophobic filter on cannula to prevent cross contamination of patients.			
	Ball switches used for body position sensors are enclosed in a plastic housing to insure patient isolation.		Ball bearing rotary sensor permanently encapsulated to ensure patient isolation.	
	Uses insulated piezoelectric sensor on effort belts to ensure patient isolation.			Uses insulated piezoelectric sensor on effort belts to ensure patient isolation.

Comparison Parameter	BIOMEC SleepFLO	Pro-Tech PTAFlite	Pro-Tech SPI Sensor	Pro-Tech Crystal Trace Piezo Respiratory Effort Sensor
Re-Use	Disposable tubing and Cannula set (single use only). Monitoring Device and respiratory effort belts and straps can be re-used	Disposable tubing and Cannula set (single use only). Monitoring Device can be re-used	Sensor pillow and wire can be re-used.	Effort belts and straps can be re-used.
Sensor Technology	Uses solid-state pressure transducer that converts small changes in air pressure into small voltage changes.	Uses solid-state pressure transducer that converts small changes in air pressure into small voltage changes		
	Uses piezoelectric transducer that converts small movements of the chest and abdomen into small voltage changes.			Uses piezoelectric transducer that converts small movements of the chest and abdomen into small voltage changes.
	Uses ball (non-mercury) switches to detect 5 body positions		Uses Gold plated ball bearing rotary sensor to detect 5 body positions.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2002

Ms. Tracey H. Wielinski
Director, Regulatory Affairs and Quality Assurance
BioMec, Incorporated
1771 East 30th Street
Cleveland, Ohio 44114-4407

Re: K020607
Trade/Device Name: SleepFLO, Model 101501
Regulation Number: 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: II
Product Code: MNR
Dated: June 17, 2002
Received: June 17, 2002

Dear Ms. Wielinski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use:

K020607

SleepFLO is intended for use during sleep disorder studies to detect up to five breathing signals: airflow, body position, thoracic effort, abdominal effort and snore.

PRESCRIPTION USE ✓

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K020607